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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Via Overnight Mail

RE: Comments on Interim Final Rule on Prior Notice of Imported Food, Docket No. 2002N-0278

Dear Sirs/Madams;

FedEx Trade Networks Transport & Brokerage, Inc., (FTN) strongly supports the efforts of the Food and Drug Administration (FDA) to protect the U.S. food supply. We respectfully offer the following comments on the interim final rules and our experiences complying with these regulations as requested in the Federal Register of April 14, 2004, Docket No. 2002N-0278.

FDA C-TPAT/FAST Questions

Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?

Yes. Food product should be eligible for full expedited processing and information transmission benefits allowed with C-TPAT and FAST. We believe the benefits of full expedited processing to be: Use of the FAST lane and a 30-minute Prior Notice (PN) time frame. Additionally, information transmission benefits will become available with the Customs and Border Protection (CBP) e-truck manifest and its reduced data elements and examinations. Further, all C-TPAT certified shippers and their products should be eligible for reduced data element reporting at the time of Prior Notice (PN) by virtue of having successfully passed the C-TPAT validation process. The product information (Harmonized Tariff Schedule number, Product Code, manufacturer's registration numbers, etc) should be part of the pre-filed information profiles under FAST.

Without these benefits, companies may not participate at the desired rates because of the resource commitment and expense associated with participation.

If the timeframe for submitting prior notice for food arriving by land via road is reduced to1 hour consistent with the timeframe in the CBP advance electronic rule, would a shorter timeframe be needed for members of FAST?

Yes. Under the CBP Advance Electronic Cargo Information rule, the time element for FAST participants is established at 30 minutes. To have two different time standards for the same mode of transportation only serves to create confusion. In the case of less than truckload (LTL) and small package carriers, the possibility

2002N-0278

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exists that freight contained in the same trailer may be subject to two different reporting time frames, one for CBP and the other for FDA.

Once again, unless there is a perceived cost benefit to Trade, participation in any program will be less than expected.

Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?"

No. The basic processes for security and verification in C-TPAT should be the same regardless of the federal agencies involved. Agencies may have their own additional requirements for specific products for which they have oversight and elevated concerns.

FDA "Flexible Alternative" Questions:

If timeframes are reduced in FDA's prior notice rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?

We believe that all other government agencies with oversight should align their processes, timeframes and benefits offered to program participants.

In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?

Participation should be voluntary. FDA should follow the existing C-TPAT program for validation of participants which includes inspection and validation of security plans.

In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the registration of food facilities interim final rule have an updated registration on file with FDA that has been verified?

Verification of registration with FDA should have been conducted under the validation aspect of the C-TPAT program.

Are there conditions of participation that FDA should consider, e.g., inspection of companies in the supply chain from the manufacturer to those who may hold the product, reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?

We understand that the C-TPAT program validation process currently provides for on-site visits, inspections, and audits of the supply chain. FDA personnel may participate in this validation process.

Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?

Participation and inclusion should be determined by a company's ability to meet the program standards required by the particular government agency with oversight authority.

If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?

Yes. To minimize confusion, the phase-in periods of shorter timeframes should be aligned and harmonized between FDA and CBP.

Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

Yes. Outreach training is always welcome.

FTN Comments on Operational Experiences under Interim Final Regulations

Prior Notice Confirmation Number (PNC): Under today's PN process, a prior notice is required for each separate and distinct food product and a PNC is returned for each prior notice. For example, if a shipment consists of multiple food products, then the carrier could have multiple PNC's to report to CBP upon arrival. This return of multiple PNC's does not align well with the commercial realities of international trade where the focus is on the entire shipment, not its individual components. Further reporting of multiple PNC's requires creation of new data fields or expansion of existing fields on transportation documents. We recommend that FDA return a PNC that encompasses the entire shipment.

FDA's definition of submitter: The interim rule defines "submitter" as: "Any person with knowledge of the required information... This person is the submitter. The submitter may also use another person to transmit the required information on his or her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person (21 CFR 1.278)." This regulation has been interpreted to require not only the corporate name and address but an individual's name, telephone number, fax number and e-mail address as well. We contend this level of detailed information is unnecessary. The information should already exist in the FDA registration database. In today's job market, individuals change jobs more frequently, thereby making maintaining this level of specificity in a database time consuming with minimal benefit. The name of the Corporation should be sufficient.

When a Prior Notice is transmitted via either the Cargo or Border Cargo Selectivity application, the date should be moved from ACS to OASIS regardless of the ETA date: FTN has experienced that if a shipments estimated time of arrival date is greater than that day's date, the data is not transmitted to FDA's OASIS immediately. The data is transmitted via an ABI batch process only at pre-determined times later that evening. However, if a Prior Notice is submitted with an ETA of the same date, the data is transmitted immediately.

In today's international trade environment, this difference in timing has become unacceptable, as many shippers are providing advance documentation so they can stage their next day's shipments to avoid border delays and additional expense. The staging, which is intended to ensure compliance with FDA's Prior Notice Regulations, is dependant upon receipt of the Prior Notice confirmation number.

Port diversions and inconsistence between agencies: Often, diversions from one port of entry to another port of entry occur for legitimate reasons. Although, the FDA PN system is designed to allow a shipment to be diverted to a port other than the intended port of entry reported in the PN, the CBP ABI system precludes the CBP entry from being accepted at other than the reported port of entry. When this occurs, the CBP entry and

original PN must be deleted and a new entry must be submitted with a new PN creating a new timeframe. This limitation makes it difficult to comply with the BTA timeframes for a PN submitted through ABI.

Line Value and Quantity Reporting for Prior Notice: These data elements are optional for admissibility purposes [801(a)] yet required for Prior Notice [801(m)]. This level of detail reporting requires large expenditures of time and manpower. We fail to see the return on this level of detail when FDA's determination will be made on information at the product code level. In addition, reducing PN reporting timeframes with no comparable reduction in data will not produce the desired benefits.

Section 321 Shipments: FDA and CBP should clarify in detail how shipments that qualify for CBP release and that require prior notice under this provision will be handled under full enforcement.

Contingency Planning: Trade's experience with the system outage on March 15, 2004 was less than satisfactory. The outage started with ABI, which included the connection to OASIS. As everyone shifted to use of Prior Notice System Interface (PNSI), PNSI was overwhelmed and failed.

FDA and CBP need to formulate and communicate a realistic contingency plan for commercial importations which takes into account CBP ABI downtime, FDA OASIS downtime and broker downtime. None of the solutions should include a dependency on PNSI as experience has shown that PNSI was intended for the casual importer and never intended for commercial operations.

Enforcement: There are continued technical problems with the systems for providing Prior Notice. PNSI is not a commercially reliable system, the CBP WP module has as yet to deliver the anticipated solutions. Until recently, ABI errors or warnings have not been returned to the transmitter resulting in a less than effective compliance outreach program. There has been a significant lack of outreach to transmitters and submitters. These shortcomings have resulted in a lack of confidence by the importing public in FDA's ability to deliver a commercially reliable system. FTN recommends that FDA and CBP extend their final phase of enforcement as a result of these delays to provide for a comparable time period equal to the originally proposed informed compliance and outreach timeframes communicated in their published phased in enforcement plan.

FTN would like to continue to work with FDA and CBP to refine the PN process so that there will be minimal adverse impact on international trade while continuing to satisfy the mandate that FDA has been given to protect the safety and security of the U.S. food supply.

Yours truly,

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